

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE
NORTHERN DIVISION**

XODUS MEDICAL, INC.,)	
ALESSIO PIGAZZI, and GLENN KEILAR,)	
)	
Plaintiffs,)	
)	
v.)	No. 3:18-cv-413-JPM
)	
PRIME MEDICAL, LLC., and)	
SYMMETRY SURGICAL INC.)	
)	
Defendants.)	

XODUS MEDICAL, INC.,)	
ALESSIO PIGAZZI, and GLENN KEILAR,)	
)	
Plaintiffs,)	
)	
v.)	No. 3:18-cv-414-JPM
)	
PRIME MEDICAL, LLC., and)	
SYMMETRY SURGICAL INC.)	
)	
Defendants.)	

XODUS MEDICAL, INC.,)	
ALESSIO PIGAZZI, and GLENN KEILAR,)	
)	
Plaintiffs,)	
)	
v.)	No. 3:18-cv-415-JPM
)	
G&T INDUSTRIES, INC.)	
)	
Defendant.)	

**ORDER DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT UNDER
SECTION 112**

Before the Court is Defendants Prime Medical LLC, Symmetry Surgical Inc., and G&T Industries, Inc.'s Motion for Summary Judgment Under Section 112, filed on October 15, 2021. (ECF No. 234.)¹ Plaintiffs filed a Response in Opposition on November 12, 2021. (ECF No. 284.) Defendants filed a Reply on November 19, 2021. (ECF No. 296.) For the reasons discussed below, the Court **DENIES** Defendants' Motion. The issue of enablement remains before the trier of fact.

I. BACKGROUND

The background of these three cases is provided in this Court's Claim Construction Order. (ECF No. 138.) This background is quoted below:

This consolidated patent action concerns devices for positioning a patient at an angle during surgery. Three patents are at issue. (ECF No. 79 at PageID 878.) Defendants in each case filed counterclaims seeking declaratory judgment of noninfringement, invalidity, and unenforceability of the subject patents. (ECF Nos. 13, 14; Case No. 3:18-cv-414, ECF Nos. 14, 16; Case No. 3:18-cv-415, ECF No. 35.)

The Technology

Some surgical procedures require a patient to be tilted during surgery. (ECF No. 95 at PageID 1334.) The Trendelenburg position is the common clinical name for when the patient is tilted so that the patient's feet are elevated. When the patient is tilted in the opposite manner, so that the patient's head is elevated over the patient's feet, the position is called the "Reverse Trendelenburg position." When the patient is tilted on the table, if insufficiently cushioned or otherwise secured, the patient may slide down the table during surgery. This can cause injury. (*Id.*)

The asserted patents are:

- (1) U.S. Patent 8,511,314 (the "'314 patent") entitled "Method of securing a patient onto an operating table when the patient is in the Trendelenburg position and apparatus therefor including a kit," which was filed on February 21, 2013, and issued on August 20, 2013.
- (2) U.S. Patent 8,464,720 (the "'720 Patent"), entitled "Method of securing a patient onto an operating table when the patient is in the Trendelenburg position and apparatus therefor including a kit," which was filed on January 9, 2013, and issued on June 18, 2013.

¹ Unless otherwise noted, all docket numbers refer to Case No. 3:18-cv-413.

(3) U.S. Patent 9,161,876 (the “’876 Patent”), entitled “Method of securing a patient onto an operating table when the patient is in the Trendelenburg position and apparatus therefor including a kit,” which was filed on August 2, 2013, and issued on October 20, 2015.

All three patents contain both method and device claims. All three patents claim priority to the same U.S. Patent App. Serial No. 13/346,852, filed January 10, 2012. (ECF No. 1-3 at PageID 33.) The ’314 Patent (ECF No. 1-2) is a continuation of the ’720 Patent, and the ’876 Patent is a continuation of both the ’314 Patent and the ’720 Patent. (Case No. 3:18-cv-414, ECF No. 1-2 at PageID 11.) The specifications of the ’314, ’720, and ’876 Patents are identical, but the claim language is not. (See, e.g., ECF No. 94 at PageID 1144.)

Xodus is a company that makes items for use in surgery, including patient positioning systems. (ECF No. 95 at PageID 1334.) Plaintiffs allege that they used their patented inventions to create and market the PINK PAD®, which is a kit that includes a set of foam materials and restraints for preventing a patient from sliding during surgery when the patient is in the Trendelenburg or Reverse-Trendelenburg position. (ECF No. 95 at PageID 1334; Declaration of Dr. Maheswari Senthil (“Senthil Decl.”), ECF No. 105-1 at PageID 1972.) Xodus asserts that the PINK PAD® met a long-felt need and had commercial success. (ECF No. 95 at PageID 1335.)

Prime and Symmetry market and sell the following models of Trendelenburg table pads: “STP100, STP100S, STP100S-WING, STP200/S, STP150 S, and STP100 PED Trendelenburg O.R. Table Pads.” (ECF No. 95 at PageID 1335.) Plaintiffs accuse these products of infringing their patents. The Defendants’ pads are blue, and for the purposes of discussion, the Court refers to the allegedly infringing pads as “the Blue Pads.” These pads were produced to the Court during the Claim Construction Hearing and are maintained as Exhibit 4. (ECF No. 123.) Prime is a medical device brand and seller that advertises pads for positioning patients in the Trendelenburg position on its website. G&T manufactures the allegedly infringing pads for Prime, and then sells the blue pads to Prime. (Case No. 3:18-cv-415, ECF No. 38 at PageID 314.) G&T explains that it has an “exclusive manufacturer/distributor relationship” with Prime, and that “G&T manufactures the products accused of infringement in both actions and supplies the accused products exclusively to Prime Medical.” (*Id.*) It does not appear that Xodus and Prime had any commercial relationship prior to this litigation, and currently they are competing in the market for surgical foam pads.

(ECF No. 138 at PageID 2880–83.)

II. LEGAL STANDARD

A party is entitled to summary judgment “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). “A fact is ‘material’ for purposes of summary judgment if proof of that fact would establish or refute an essential element of the cause of action or defense.” Bruederle v. Louisville Metro Gov’t, 687 F.3d 771, 776 (6th Cir. 2012).

“In considering a motion for summary judgment, [the] court construes all reasonable inferences in favor of the nonmoving party.” Robertson v. Lucas, 753 F.3d 606, 614 (6th Cir. 2014) (citing Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986)). “The moving party bears the initial burden of demonstrating the absence of any genuine issue of material fact.” Mosholder v. Barnhardt, 679 F.3d 443, 448 (6th Cir. 2012) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986)).

“Once the moving party satisfies its initial burden, the burden shifts to the nonmoving party to set forth specific facts showing a triable issue of material fact.” Mosholder, 679 F.3d at 448–49; see also Fed. R. Civ. P. 56(e); Matsushita, 475 U.S. at 587. “When the non-moving party fails to make a sufficient showing of an essential element of his case on which he bears the burden of proof, the moving parties are entitled to judgment as a matter of law and summary judgment is proper.” Martinez v. Cracker Barrel Old Country Store, Inc., 703 F.3d 911, 914 (6th Cir. 2013) (quoting Chapman v. UAW Local 1005, 670 F.3d 677, 680 (6th Cir. 2012) (en banc)); see also Kalich v. AT & T Mobility, LLC, 679 F.3d 464, 469 (6th Cir. 2012).

To “show that a fact is, or is not, genuinely disputed,” both parties must do so by “citing to particular parts of materials in the record,” “showing that the materials cited do not establish the absence or presence of a genuine dispute,” or showing “that an adverse party cannot produce

admissible evidence to support the fact.” Bruederle, 687 F.3d at 776 (quoting Fed. R. Civ. P. 56(c)(1)); see also Mosholder, 679 F.3d at 448 (“To support its motion, the moving party may show ‘that there is an absence of evidence to support the nonmoving party’s case.’” (quoting Celotex Corp., 477 U.S. at 325)). “Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge[.]” Martinez, 703 F.3d at 914 (alteration in original) (quoting Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986)).

“The court need consider only the cited materials, but it may consider other materials in the record.” Fed. R. Civ. P. 56(c)(3). “[T]he district court has no ‘duty to search the entire record to establish that it is bereft of a genuine issue of material fact.’” Pharos Capital Partners, L.P. v. Deloitte & Touche, 535 F. App’x 522, 523 (6th Cir. 2013) (per curiam) (quoting Tucker v. Tennessee, 539 F.3d 526, 531 (6th Cir. 2008), abrogation recognized by Anderson v. City of Blue Ash, 798 F.3d 338 (6th Cir. 2015)). “[J]udges are not like pigs, hunting for truffles’ that might be buried in the record.” Emerson v. Novartis Pharm. Corp., 446 F. App’x 733, 736 (6th Cir. 2011) (alteration in original) (quoting United States v. Dunkel, 927 F.2d 955, 956 (7th Cir. 1991)).

The decisive “question is whether ‘the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.’” Johnson v. Memphis Light Gas & Water Div., 777 F.3d 838, 843 (6th Cir. 2015) (quoting Anderson, 477 U.S. at 251–52). Summary judgment “‘shall be entered’ against the nonmoving party unless affidavits or other evidence ‘set forth specific facts showing that there is a genuine issue for trial.’” Rachells v. Cingular Wireless Emp. Servs., LLC, No. 1:08CV02815, 2012 WL 3648835, at *2 (N.D. Ohio Aug. 23, 2012) (quoting Lujan v. Nat’l Wildlife Fed’n, 497 U.S. 871, 888 (1990)). “[A] mere ‘scintilla’ of evidence in support of the non-moving party’s position is

insufficient to defeat summary judgment; rather, the non-moving party must present evidence upon which a reasonable jury could find in her favor.” Tingle v. Arbors at Hilliard, 692 F.3d 523, 529 (6th Cir. 2012) (quoting Anderson, 477 U.S. at 251). “[I]n order to withstand a motion for summary judgment, the party opposing the motion must present ‘affirmative evidence’ to support his/her position.” Mitchell v. Toledo Hosp., 964 F.2d 577, 584 (6th Cir. 1992) (citing Anderson, 106 S. Ct. at 2514; Street v. J.C. Bradford & Co., 886 F.2d 1472, 1479 (6th Cir. 1989)). “[C]onclusory assertions, unsupported by specific facts made in affidavits opposing a motion for summary judgment, are not sufficient to defeat a motion for summary judgment.” Rachells, 2012 WL 3648835, at *2 (quoting Thomas v. Christ Hosp. & Med. Ctr., 328 F.3d 890, 894 (7th Cir. 2003)). Statements contained in an affidavit that are “nothing more than rumors, conclusory allegations and subjective beliefs” are insufficient. Mitchell, 964 F.2d at 584–85.

III. ANALYSIS

A. Indefiniteness

Defendants seek summary judgment of invalidity “because key claim terms are indefinite.” (ECF No. 234 at PageID 4601.) “[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S. 898, 901 (2014). This requirement “mandates clarity, while recognizing that absolute precision is unattainable.” Id. at 910. Defendants contend that the following claim terms render the claims indefinite: (1) “minimizing injuries,” (2) “minimizing undesired movement,” (3) “sufficient thickness and viscosity to sufficiently cushion,” and (4) “a rate of recovery sufficiently slow to maintain a depression in said pad for a desired period of time.”

(ECF No. 234 at PageID 4602–05.) Each of these terms was construed and held not indefinite in this Court’s Claim Construction Order. (See ECF No. 138 at PageID 2900, 2913, 2916, 2919.)

Because the Court found these terms not indefinite during claim construction, Plaintiffs contend that the Court should find them not indefinite once again. (ECF No. 284 at PageID 8197–200.) In reply, Defendants contend that “the presence of newly available extrinsic evidence—namely, the testimony of the parties’ respective expert witnesses—means that the question of claim definiteness is ripe for (re)consideration by this Court at the present juncture.” (ECF No. 296 at PageID 9036.) The cases cited in support of changing the Court’s finding of indefiniteness, however, allowed reconsideration of indefiniteness because of a change in the legal standard for indefiniteness that occurred during the case at issue. See Dow Chem. Co. v. Nova Chem. Corp. (Canada), 803 F.3d 620, 624 (Fed. Cir. 2015) (“We hold that the intervening change in the law of indefiniteness resulting from Nautilus provides an exception to the doctrine of law of the case or issue preclusion.”); ACQIS LLC v. Alcatel-Lucent USA Inc., No. 6:13-CV-638, 2015 WL 1737853, at *1, *9 (E.D. Tex. Apr. 13, 2015) (“The Court has already construed some of the terms at issue here in a previous case. See ACQIS LLC v. Appro Int’l, Inc. et. al., No 6:09-cv-148, Docket No. 315 (E.D. Tex. Aug. 2, 2010) (‘Appro’).”) (“In Appro, the Court applied the ‘insolubly ambiguous’ standard to find the term ‘similar in design’ did not render the claims indefinite. . . . The Supreme Court abrogated the ‘insolubly ambiguous’ standard in Nautilus.”).

Even upon reconsideration of the issue of indefiniteness, the supposed addition of expert witness evidence does not change the arguments or analysis from the parties here. In the single instance where Defendants refer to expert testimony in their Motion’s indefiniteness analysis, it is from Dr. Reynolds’s Declaration that was already used during claim construction. (See ECF No. 234 at PageID 4603.) (citing Declaration of J.M. Reynolds, M.D., ECF No. 96-2.) As a result,

Defendants have not proffered any new evidence to consider regarding indefiniteness, and Defendants' Motion is **DENIED** as to indefiniteness.

B. Lack of Enablement

In the alternative, Defendants contend that the claims are invalid for lack of enablement. (Id. at PageID 4607.) “The requirement of enablement, stated in 35 U.S.C. § 112, enforces the essential ‘*quid pro quo* of the patent bargain’ by requiring a patentee to teach the public how ‘to practice the full scope of the claimed invention.’” McRO, Inc. v. Bandai Namco Games Am. Inc., 959 F.3d 1091, 1099–1100 (Fed. Cir. 2020) (citing AK Steel Corp. v. Sollac, 344 F.3d 1234, 1244 (Fed. Cir. 2003)). “Once the precise scope of the claimed invention is defined, the question is whether undue experimentation is required to make and use the full scope of embodiments of the invention claimed.” Id. at 1100. The “[f]actors to be considered in determining whether a disclosure would require undue experimentation” include:

- (1) The quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

Defendants contend that the claims are not enabled because they (1) “necessitate an excessive quantity of experimentation”; (2) “present woefully inadequate direction or guidance and provide no working examples”; and (3) contain overly broad claims. (ECF No. 234 at PageID 4608–09, 4612.) Plaintiffs dispute each of these assertions and in addition, contend that Defendants failure to “identify any specific embodiment with[in] the scope of the claims that is not enabled” and Defendant’s failure to take into consideration the fourth Wands factor, “the nature of the invention,” means Defendants have not met their burden to prove lack of enablement. (ECF No. 284 at PageID 8202–09.) Plaintiffs also assert that the Court should deny Defendant’s lack of

enablement theory because it was inadequately disclosed. (Id. at PageID 8202.) The Court first addresses Plaintiffs’ contentions regarding disclosure and the fourth Wands factor and then analyzes the Wands factors raised by Defendants in their Motion.

i. Adequacy of Disclosure

Plaintiffs first assert that, because Defendants did not adequately disclose this invalidity theory, Defendants “should not be heard on their new contention now.” (Id. at PageID 8202.) Defendants, in reply, contend that “Defendants’ theory of invalidity for lack of enablement was timely disclosed. . . . Defendants’ invalidity contentions gave notice of Defendants’ theory that the asserted patent claims are not enabled because, among other reasons, the patent specifications do not provide adequate direction or guidance, and hence require undue experimentation.” (ECF No. 296 at PageID 9037.) The Court finds that there was sufficient disclosure in Defendants’ invalidity contentions. (See, e.g., Defendants’ First Set of Supplemental Contentions Regarding Invalidity, ECF No. 196-3 at PageID 3872.) (“[A] person of ordinary skill in the art has no choice but to engage in an ad hoc trial-and-error process of changing known characteristics of the material”))

ii. Requirement of a Specific Embodiment that Is Not Enabled

Plaintiffs also contend in their Response that the Court should deny Defendants’ lack of enablement theory because “Defendants have identified no specific subject matter or embodiment that [they] believe[] is within the scope of the claims and is not enabled.” (ECF No. 284 at PageID 8204.) Plaintiffs cite to Federal Circuit case law that states ““the Wands analysis has routinely involved concrete identification of at least some embodiment or embodiments asserted not to be enabled—including what particular products or processes are or may be within the claim, so that breadth is shown concretely and not just [as] an abstract possibility.”” (Id. at PageID 8203.)

(quoting McRO, Inc., 959 F.3d at 1101.) Defendants, however, contend that “Plaintiffs’ argument hinges on a misreading of the Federal Circuit’s decision in McRO Plaintiffs would have us read ‘*routinely*’ as equivalent to ‘*necessarily*’—a reading not supported by the cited precedent or other case law.” (ECF No. 296 at PageID 9038–39.) (emphasis in original.)

Defendants contend that this matter is distinguishable from McRO because “Plaintiffs have identified the Accused Products and have identified Plaintiffs’ own products that embody the claimed invention and compete with the Accused Products”; they contend that the issue of enablement here is “whether the specification does or does not enable a pad with the recited performance characteristics.” (*Id.* at PageID 9039.) The Court agrees that, here, there is a concrete question of enablement rather than a mere “abstract possibility.” McRO, Inc., 959 F.3d at 1101. Defendants’ Motion does not fail on this basis, and the Court will next examine the Wands factors.

iii. The Fourth Wands Factor: The Nature of the Invention

Plaintiffs contend that “Defendants’ analysis of the following Wands factors fails to take the nature of the invention into account” because Defendants “treat the specifications as if they are required to disclose specific formulations of foam, instead of providing a set of guidelines that can be utilized by a PHOSITA to make and use the claimed inventions with anyone of a variety of foams within the viscoelastic family.” (ECF No. 284 at PageID 8204.) Defendants, however, contend that “Plaintiffs’ appeal to Factor 4 of the Wands list does not help their case and does not change the overall enablement analysis.” (ECF No. 296 at PageID 9040.) They contend that, instead:

The problem, fundamentally, is that the “set of guidelines” provided by the specification is, at bottom, a set of broad, vague functional limitations that are too nebulous to effectively guide a PHOSITA to select a correct foam from within the expansive genus of viscoelastic foams. The specification fails to enable, not because it lacks guidelines, but because those guidelines are themselves too vague to be useful even to a PHOSITA. Particularly with regard to the apparatus claims,

the “guidelines” do not tell a PHOSITA what the viscoelastic foam is, as opposed to what it does.

(Id.) Thus, based on both Parties briefing and dueling expert testimony, there appears to be a dispute of fact as to whether the guidelines are sufficient for a PHOSITA.

iv. The First Wands Factor: Amount of Experimentation Necessary

Defendants contend that “[t]he disclosure here does not adequately guide a physician, or a foam expert, to determine, without undue experimentation, which of the ‘thousands’ of available viscoelastic foams might exhibit the performance characteristics needed to ‘minimize movement’ or ‘minimize injuries,’ or which foams would have ‘sufficient thickness and viscosity to sufficiently cushion. . . .’” (ECF No. 234 at PageID 4608.) In support of this contention, Defendants cite to the reexamination hearing testimony of the ’720 Patent, where counsel for Plaintiffs made the following statements:

In addition, it wouldn’t be obvious to try because we’re not looking at a finite series of solutions. There are simply thousands of different types of viscoelastic foam. Some are hard as a rock and require a large amount of force to be supplied in order to deform. Some are very compliant and soft. So it would take undue experimentation in order to come up with a solution that would work properly in this very specific claimed environment.

....

You simply couldn’t look to any viscoelastic. You would have to test various viscoelastic foams in order to be able to get that property to assist in the holding of the patient.

(See ECF No. 234-4 at PageID 4712–14.)

In response, Plaintiffs contend that “[t]hese statements [by Plaintiffs’ counsel], however, were made in the context of nonobviousness of the claims in view of various pieces of prior art,” and that “the USPTO did not indicate that the claims were to be limited to any specific foam.” (ECF No. 284 at PageID 8205.) Further, Plaintiffs contend that “[e]ach of the Patents-in-Suit includes values for claimed limitations, such as the rate of recovery, ball rebound, compression

set, indentation force deflection, etc.,” and that “[t]hese values provide a PHOSITA with insight into the family of viscoelastic foams that may be used in the claimed inventions.” (Id. at PageID 8206.)

In reply, Defendants assert that “Plaintiffs conveniently fail to mention that the so-called ‘detailed numbers or ranges of numbers for various claim parameters’ in the specifications are incorporated into the dependent claims (for example, claims 3, 5, and 9 in the ’720 patent),” so “[t]he doctrine of claim differentiation creates a presumption that these dependent claim limitations are not included in the independent claim.” (ECF No. 296 at PageID 9042.) (citing GE Lighting Sols., LLC v. AgiLight, Inc., 750 F.3d 1304, 1310 (Fed. Cir. 2014); Intellectual Ventures I LLC v. Symantec Corp., 838 F.3d 1307, 1321–22 (Fed. Cir. 2016).)

Overall, on this factor there remains a dispute of fact as to the amount of experimentation needed to determine whether a viscoelastic foam could be used to practice the invention. For example, Plaintiffs cite to Mr. DePhillipo’s testimony “that a skilled artisan would be able to rely on the features of the viscoelastic foam disclosed in the specifications of the Patents-in-Suit to understand the claimed invention,” which contradicts Defendants’ above-mentioned factual contentions that indicate an undue amount of experimentation would be needed. (ECF No. 284 at PageID 8207.) (citing ECF No. 95-4 at PageID 1450–51.) As for Defendants’ contention regarding claim differentiation, the cited cases were on appeal for claim construction, and, as the Court has already construed the applicable claims of the asserted patents (see ECF No. 138), such an argument is untimely.

v. The Second and Third Wands Factors: Direction/Guidance and Working Examples

Defendants contend that “[t]he patents-in-suit provide woefully inadequate direction or guidance for selecting a suitable ‘deformable material’ or viscoelastic foam that would satisfy the

functional limitations of the claims, and the specification provides no working examples.” (ECF No. 234 at PageID 4609.) Defendants assert that “[t]he Federal Circuit has explained that ‘there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill in the art how to make and how to use the invention as broadly as it is claimed.’” (Id.) (citing In re Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991).) Defendants contend that Plaintiffs’ expert, Alexander B. Olawaiye, M.D.’s (“Dr. Olawaiye”) testimony supports this contention because:

Dr. Olawaiye knows that Plaintiffs’ commercial embodiment, the Pink Pad, meets the requirement of having “a rate of recovery sufficiently slow to maintain a depression in said pad for a desired period of time”; but Dr. Olawaiye is unable to provide a range of recovery times that would fall within the coverage of this limitation: he “can’t put a number to that.”

(Id. at PageID 4610.) (citing Dr. Olawaiye Dep., 206:1–208:5.) As a result, Defendants contend that “[t]here is no genuine issue of material fact related to this factor because the absence of working guidance, or working examples, is so stark.” (Id. at PageID 4611.)

In response, Plaintiffs contend that “Defendants again ignore the portions of the specifications at issue (*i.e.*, ’720 Patent at 2:25-3:30) providing different values for the different parameters that would lead a PHOSITA to make and use the claimed viscoelastic foam pad.” (ECF No. 284 at PageID 8207.) Plaintiffs also assert that “the Defendants again ignore any evidence from Mr. DePhillipo that would suggest the specifications provide the necessary guidance and direction to allow a PHOSITA to make and/or use the claimed inventions.” (Id.) (citing ECF No. 95-4 at PageID 1450–51 as an example.)

Once again, like with the first Wands factor, evaluating the amount of experimentation necessary, there is a factual dispute with expert testimony in support of each Party’s position.

vi. The Sixth Wands Factor: Relative Skill of Those in the Art

“[A] specification need not disclose what is well known in the art.” Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 1366 (Fed. Cir. 1997). To have an “adequate enabling disclosure in the specification,” however, a patentee “cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification.” ALZA Corp. v. Andrx Pharm., LLC, 603 F.3d 935, 941 (Fed. Cir. 2010).

Defendants contend that, per Plaintiffs’ counsel’s arguments in the re-examination hearing, the PHOSITA “is a physician or a doctor, and they aren’t going to have the knowledge of foams that a foam manufacturer will have, so they wouldn’t know what type of foam to look for.” (ECF No. 234 at PageID 4612.) (citing ECF No. 234-4 at PageID 4714.) As a result, Defendants contend the alleged insufficiencies in the specification “cannot be cured by appeal to the skill of those in the art. Even persons of ordinary skill in the art need some starting point and guidelines for implementing the invention.” (Id.)

Plaintiffs, in response, contend that “this Court has determined that a PHOSITA ‘would appreciate the significant aspects of foam materials used in Trendelenburg surgical kits,’” which indicates “that the PHOSITA would be able to understand the parameters described in the specifications as they relate to viscoelastic foam pads used in the Trendelenburg procedure.” (ECF No. 284 at PageID 8208.) (citing ECF No. 138 at PageID 2894.)

Here, much like with the other factors, Plaintiffs have established a factual dispute as to whether the properties in the specification would be sufficient for a PHOSITA to use or make the invention.

vii. The Eighth Wands Factor: Breadth of the Claims

Next, Defendants contend that the eighth Wands factor also favors summary judgment as to lack of enablement because “the asserted claims are shockingly broad. Plaintiffs’ statements

and arguments during this litigation bolster the conclusion that the asserted claims have a broad scope—a broad scope that is not matched by correspondingly broad disclosure.” (ECF No. 234 at PageID 4613.) Plaintiffs contend, however, that “the claims recite very specific performance parameters and properties of the foam, which are ignored by Defendants.” (ECF No. 284 at PageID 8209.) Overall, this factor, on balance, is neutral in determining enablement in this case, because the claim scope does have some limiting parameters in the specification, but in other motions, the Plaintiffs have argued that the claims cover all types of viscoelastic foam. (See, e.g., ECF No. 307 at PageID 9155–56.) (“The Accused Products, then, need only to be a viscoelastic foam to infringe this previously construed feature.”) (“Rather, the only question as to whether the Accused Products meet this limitation is whether they are made of viscoelastic foam.”)

Enablement is a matter of law with many factual underpinnings. See McRO, Inc., 959 F.3d at 1096 (“[W]hether a patent satisfies enablement is a question of law based on underlying factual findings.”); ALZA Corp., 603 F.3d at 940 (“[W]hether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations.”) (citing Wands, 858 F.2d at 737.) Many of the Wands factors here turn on disputes of fact as to whether they support a finding of enablement. As such, it would be improper for the Court to grant summary judgment as to whether the claims are enabled without supplemental findings of fact weighed by the jury. As a result, Defendants’ Motion as to lack of enablement is **DENIED**.

IV. CONCLUSION

For the foregoing reasons, Defendants' Motion for Summary Judgment Under Section 112 is **DENIED**.

IT IS SO ORDERED, this 20th day of December, 2021.

/s/ Jon P. McCalla
JON P. McCALLA
UNITED STATES DISTRICT JUDGE